GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2205
ANSWERED ON:17.12.2003
MARKETING OF LETROZOLE
A.K. PREMAJAM;BALIRAM;DINESH CHANDRA YADAV;PUSHPDAN SHAMBHUDAN GADHAVI;RAM JEEVAN SINGH;RAM VILAS PASWAN

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government is aware of the unregulated marketing of Letrozole, an anti-cancer drug for women, by Mumbai based Sun Pharmaceuticals as reported in the Hindustan Times dated September 24, 2003;

(b) if so, the facts of the matter;

(c) whether it has the approval of the Drug Controller General of India (DCGI); and

(d) if not, the action taken/being taken by the Government against the company?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) to (d): Yes Sir. In a news item appearing in Hindustan Times, New Delhi dated 24.9.2003, it was reported that Letrozole, an oral anticancer drug is being marketed in the country for fertility enhancement in women by M/s. Sun Pharmaceuticals, Mumbai. Letrozole had been approved for M/s. Sun Pharmaceuticals on 28th June, 2001, as a second line treatment of advanced breast cancer in women.

Since, no formal approval was issued for the use of Letrozole as a fertility drug, the firm was issued a notice on 25.9.2003 to explain their alleged promotion of Letrozole as a fertility drug.

It has been explained by the concerned firm that they did not make any claim about its use in fertility on label of their product. However, following the published literature about beneficial use of letrozole in fertility enhancement, gynecologists who enquire about its use in fertility were provided relevant information. After examining the clarification given by the firm and published literatures on Letrozole, M/s Sun Pharmaceuticals, have been issued serious `Warning` to refrain from any such promotional activity, which may induce off label use of Letrozole for fertility, and to destroy all relevant promotional material claiming its use in unapproved indications. An advisory that Letrozole has not been approved as treatment for infertility has been issued to all States.